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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/024,143

12/21/2001

John S. Bobo

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45473 7590 07/10/2006

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EXAMINER

VANIK, DAVID L

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 07/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/024,143	<b>Applicant(s)</b> BOBO ET AL.	
	<b>Examiner</b> David L. Vanik	<b>Art Unit</b> 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 May 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 4-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Receipt is acknowledged of the Applicant's amended claims and remarks filed on 5/3/2006.

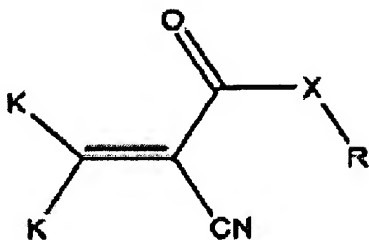
As a result of Applicant's amended claims, the 35 U.S.C. 102 rejections over US 2,784,127 ('127) and US 3,527,841 ('841) are hereby **withdrawn**.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

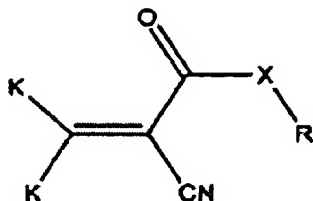
Claims 4-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a very defined structure with the below formula wherein "X" is "NR" and "[R'-X]" is an amino acid residue, does not reasonably provide enablement for the below structural formula wherein "X" is "O," "S," or "Se" and "[R'-X]" is an amino acid residue. The structural compound at issue has the following structural formula:



The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include: breadth of the claims; nature of the invention; state of the prior art; amount of direction provided by the inventor; the level of predictability in the art; the existence of working examples; quantity of experimentation needed to make or use the invention based on the content of the disclosure; and relative skill in the art. All of the factors have been considered with regard to the claim, with the most relevant factors discussed below:

**The breadth of claims:** The instant claims 4-7 are drawn to the following compound:



wherein:

K is H;

X is O, NR, S or Se;

R is absent, -H, -(CH<sub>2</sub>)<sub>n</sub>alkyl, -(CH<sub>2</sub>)<sub>n</sub>alkenyl, -(CH<sub>2</sub>)<sub>n</sub>alkynyl, -(CH<sub>2</sub>)<sub>n</sub>cycloalkyl, -(CH<sub>2</sub>)<sub>n</sub>heterocyclyl, -(CH<sub>2</sub>)<sub>n</sub>aryl or -(CH<sub>2</sub>)<sub>n</sub>heteroaryl;

n is an integer from 0 to 10;

R' is a substituted organic residue; and

[R'-X] comprises an amino acid residue.

It should be noted that specific amino acids are enumerated in the instant claims 5-7.

**The nature of the invention:** In contrast to the claims, the invention is drawn to a limited compound. As set forth in paragraph 0128 of the instant specification, the [R'-X] residue has a structure wherein "X" is "NR" and "R" is CH(Z)-CO-. This is consistent with the basic structure of an amino acid residue. Moreover, as set forth in paragraphs 0108 - 0128, "R" may comprise a substituent group only such that it is compatible with the limitation of the [R'-X] group comprising an amino acid. Thus, after carefully considering the scope of the instant specification (especially paragraphs 0108 - 0129), the examiner respectfully asserts that the instant claim set is only enabled such that the [R'-X] residue has a structure wherein "X" is "NR" and "R" is CH(Z)-CO-. That is, consistent with the instant specification and amended claim set, [R'-X] is enabled to the extent that it has a structure corresponding to an amino acid residue.

**The amount of direction provided by the inventor:** There is nothing in the specification that would indicate that the current composition could comprise the above structure herein "X" is "O," "S," or "Se." Moreover, there is nothing in the instant specification that indicates that "R" can be "absent" or any alkyl, alkenyl, alkynyl, or aryl group. Rather, consistent with the instant specification, when [R'-X] is an amino acid residue "X" is "NR." Specifically, as set forth in the instant paragraph 0128, when [R'-X] is an amino acid residue, "X" is "NR" and "R'" is CH(Z)-CO-. The examiner respectfully asserts that "R" can be any of the alkyl, alkenyl, alkynyl, or aryl groups as long as they are consistent with [R'-X] being an amino acid residue (and "n" being an integer between 0 to 10). The examiner respectfully asserts that guidance for preparing and using a composition comprising the above structure wherein [R'-X] is an amino acid residue and "X" is "O," "S," or "Se" is not provided in the instant specification. With respect to the instant composition, there is a substantial gap between a composition comprising the above structure wherein [R'-X] is an amino acid residue and "X" is "NR" and a composition comprising the above structure wherein [R'-X] is an amino acid residue and "X" is "O," "S," or "Se." Consequently, a burdensome amount of research would be required by one of ordinary skill in the art to bridge this gap.

**The quantity of experimentation:** As stated above, the examiner respectfully asserts that guidance for preparing and using a composition comprising the above structure wherein [R'-X] is an amino acid residue and "X" is "O," "S," or "Se" is not

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provided in the instant specification. With respect to the instant composition, there is a substantial gap between a composition comprising the above structure wherein [R'-X] is an amino acid residue and "X" is "NR" and a composition comprising the above structure wherein [R'-X] is an amino acid residue and "X" is "O," "S," or "Se."

Consequently, a burdensome amount of research would be required by one of ordinary skill in the art to bridge this gap.

**The relative skill of those in the art:** the skill of one of ordinary skill in the art is very high, e.g., Ph.D. and M.D. level technology.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent 5,041,602 ('602) is cited as patents of interest in its disclosure of a amino acid-based compound. Like the instant application, the '602 compound comprises an amino acid-based composition comprising cyano and carbonyl groups (See structure "1b" at column 2, lines 53-60). Unlike the instant claimed composition, however, both "K" groups are not hydrogen. Although one "K" group in '602 can be hydrogen, the second "K" group is a long-chain optically active group.

Additionally, Chabaka et al. (Amino Acid Derivatives in Organic Synthesis is cited as patents of interest in its disclosure of a amino acid-based compound. Specifically, compounds "3a" and "3b" on page 106 disclose an amino acid-based compound. However, although one "K" group is hydrogen, the second "K" group is a Phenyl group.

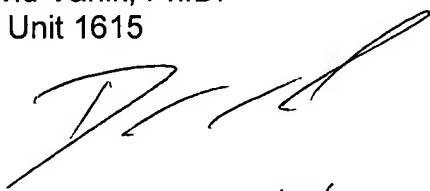
**Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Vanik whose telephone number is (571) 272-3104. The examiner can normally be reached on Monday-Friday 8:30 AM - 5:00 PM.

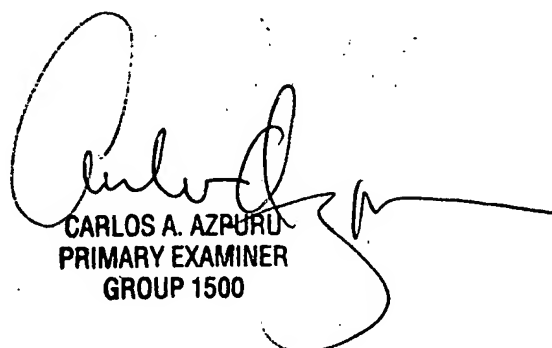
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Vanik, Ph.D.  
Art Unit 1615



6/30/06



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